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Registration Decision

RD2012-04

Methyl Anthranilate

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Registration Decision for Methyl Anthranilate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Methyl Anthranilate Technical and Rejex-It Migrate for Agriculture and Turf Bird Repellent, containing the technical grade active ingredient methyl anthranilate, to repel a variety of birds in cherries and blueberries, as well as Canada geese on turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2011-11, *Methyl Anthranilate*. This Registration Decision² describes this stage of the PMRA's regulatory process for methyl anthranilate and summarizes the Agency's decision. The PMRA received no comments on PRD2011-11. This decision is consistent with the proposed registration decision stated in PRD2011-11.

For more details on the information presented in this Registration Decision, please refer to PRD2011-11, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Methyl Anthranilate?

Methyl anthranilate repels birds when it comes in contact with eyes, nostrils and mouths. It has been registered in Canada to repel Canada geese from turf since 2000. In addition to this use, the end-use product Rejex-It Migrate for Agriculture and Turf Bird Repellent is also used to repel birds from cherries and blueberries.

Health Considerations

Can Approved Uses of Methyl Anthranilate Affect Human Health?

Methyl anthranilate is unlikely to affect your health when used according to label directions.

Methyl anthranilate is a natural component in a variety of plants and fruits. Potential exposure to methyl anthranilate may occur when handling and applying the end-use product or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, Methyl Anthranilate Technical, is of low acute toxicity by the oral and dermal routes and is mildly irritating to the eyes, but is not an irritant or potential sensitizer to the skin. Methyl Anthranilate Technical is expected to be of low acute toxicity via the pulmonary route. Therefore, precautionary statements alerting users to the eye irritation potential were required on the labels for Methyl Anthranilate Technical.

The end-use product, Rejex-It Migrate for Agriculture and Turf Bird Repellent, is of low acute toxicity by the oral and dermal routes, is minimally irritating to the eyes, and is not an irritant or potential sensitizer to the skin. Rejex-It Migrate for Agriculture and Turf Bird Repellent is expected to be of low acute toxicity via the pulmonary route.

Requests to waive short-term dermal toxicity, prenatal development toxicity and genotoxicity studies were accepted by the PMRA. Waivers were based on the low toxicity profile, the rapid metabolism into excreted byproducts and on the strength of evidence that there is little indication of short or long term toxic effects resulting from methyl anthranilate's long history as an additive in food products.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

At the time of harvest, the residue level of crops treated with methyl anthranilate is not expected to exceed the natural levels occurring in commonly consumed foods, such as grapes. Therefore, no crop residue data are needed and the establishment of an MRL will not be required.

While good hygiene practices, such as washing food prior to eating, are not considered in the assessment for the registration of a food-use pesticide, they are recommended as any remaining residues are likely to be further decreased by washing and possible cooking of treated crop before eating.

Occupational Risks from Handling Rejex-It Migrate for Agriculture and Turf Bird Repellent

Occupational risks are not of concern when Rejex-It Migrate for Agriculture and Turf Bird Repellent is used according to label directions, which include protective measures.

Occupational exposure to individuals mixing, loading, or applying Rejex-It Migrate for Agriculture and Turf Bird Repellent is not expected to result in unacceptable risk when the product is used according to label directions.

Inhalation and dermal exposures are likely for occupational workers and commercial applicators. Anyone entering the sprayed areas before the spray is dried may be exposed dermally. Therefore, personal protective equipment and a restricted entry statement (i.e. until sprays have dried) were required on the end-use product label to mitigate such exposure concerns.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible if the precautionary label statements are observed.

Precautionary (for example, wearing of personal protective equipment) statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Methyl Anthranilate Is Introduced Into the Environment?

Environmental risks to non-target organisms are not of concern when Rejex-It Migrate for Agriculture and Turf Bird Repellent is used according to label directions, which include precautionary label statements and buffer zones.

Methyl anthranilate enters the environment when it is sprayed on turf, cherries, and blueberries to repel birds. It is not expected that methyl anthranilate will pose a risk to terrestrial species given its low toxicity to terrestrial organisms. However, methyl anthranilate has been shown to cause adverse effects in aquatic organisms. Because of the high application rates used in cherry and blueberry, a potential for concern for aquatic organisms has been identified in these crops should methyl anthranilate enter the aquatic environment through spray drift. Methyl anthranilate will not likely reach surface water through run-off or leach through the soil profile and contaminate groundwater due to its rapid dissipation.

Value Considerations

What Is the Value of Rejex-It Migrate for Agriculture and Turf Bird Repellent

Methyl anthranilate repels birds such as American robins, house finches, sparrows and European starlings from blueberries and cherries, and Canada geese from turf. It is an additional product to use in a bird control program.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Rejex-It Migrate for Agriculture and Turf Bird Repellent to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

The signal words "CAUTION EYE IRRITANT" and the statement "May irritate eyes. Avoid contact with eyes." are present on the principal and the secondary display panels, respectively, of the label for Methyl Anthranilate Technical.

The precautionary statement "Avoid contact with skin, eyes or clothing" is present on the secondary display panel of the label for Rejex-It Migrate for Agriculture and Turf Bird Repellent. Also the label recommends the product be mixed outside or in a ventilated area.

The label for Rejex-It Migrate for Agriculture and Turf Bird Repellent requires applicators and other handlers to wear long-sleeved shirt and long pants, waterproof gloves, shoes plus socks.

To prevent post-application exposure, the label for Rejex-It Migrate for Agriculture and Turf Bird Repellent states to "allow material to dry before permitting human activity in the treated areas".

To prevent bystander exposure when used on golf courses and municipal parks, the label restricts the use of Rejex-It Migrate for Agriculture and Turf Bird Repellent by stating "Do not apply the end-use product to residential lawns or recreational areas of parks."

Environment

To mitigate the risk to aquatic organisms from spray drift, buffer zones up to five metres for cherry and two metres for blueberry must be observed. No buffer zones are required for turf uses, as the application rate is lower and is not expected to cause adverse effects to non target aquatic organisms.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-11, *Methyl Anthranilate*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.